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Date: August 12, 2002 By: Tom Brody

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Debets, et al.

Serial No.: 09/775,046

Filed: February 1, 2001

For: MAMMALIAN CYTOKINES;  
RECEPTORS; RELATED  
REAGENTS AND METHODS

Examiner: S. Prasad

Art Unit: 1646

### RESPONSE TO RESTRICTION REQUIREMENT

Palo Alto, California 94304

August 30, 2002

Assistant Commissioner for Patents  
Washington, D.C. 20231

Honorable Sir:

This is a response to the Restriction Requirement dated July 2, 2002 (Paper 8). Accompanying this response is a petition for a one-month extension of time and fee, thereby extending the time to respond from August 2, 2002 to September 3, 2002 (Sept. 2, 2002 is a Federal holiday).

The Examiner restricted the application into eleven separate inventions:

- I. Claims 1-3, drawn to a method of producing a ligand: receptor complex, comprising contacting a mammalian IL-1 $\delta$  or IL-1 $\epsilon$  with a receptor comprising the IL-1R6 receptor subunit, classified in class 435, subclass 7.1.

- II. Claims 4-7, drawn to methods of modulating a physiological signal by contacting an IL-1R6 receptor bearing cell with an antibody to IL-1 $\delta$ , or antibody to IL-1 $\epsilon$ , classified in class 435, subclass 7.1.
- III. Claims 8-11, drawn to modulation of a signal to a cell mediated by IL-1 $\delta$  or IL-1 $\epsilon$  comprising contacting the cell with antibody to IL-1R6 receptor, classified in class 435, subclass 7.1.
- IV. Claims 12-15, drawn to identification of cells by selectively labeling a population of cells with an IL-1R6 antibody, or a cytokine selected from IL-1 $\delta$  or IL-1 $\epsilon$ , and cells purified by the instant methods, classified in class 435, subclass 7.1.
- V. Claims 16-17, drawn to a method of testing a compound for ability to affect IL-1R6 receptor-ligand interaction, the method comprising comparing the interaction of IL-1R6 with IL-1 $\delta$ , or IL-1 $\epsilon$ , in the presence and absence of the compound, classified in class 435, subclass 7.1.
- VI. Claim 18, drawn to isolated or recombinant polynucleotide of SEQ ID NO:1 encoding polypeptides of SEQ ID NO:2, classified in class 435, subclass 69.1.
- VII. Claim 18, drawn to an isolated or recombinant polynucleotide of SEQ ID NO:3 encoding polypeptides of SEQ ID NO:4, classified in class 435, subclass 69.1.
- VIII. Claim 19, drawn to isolated or recombinant polypeptide of SEQ ID NO:2, classified in class 530, subclass 350.
- IX. Claim 19, drawn to isolated or recombinant polypeptide of SEQ ID NO:4, classified in class 530, subclass 350.
- X. Claim 20, drawn to a binding compound comprising an antigen-binding portion from an antibody, which binds with selectivity to SEQ ID NO:2, classified in class 530, subclass 387.7.
- XI. Claim 20, drawn to a binding compound comprising an antigen-binding portion from an antibody, which binds with selectivity to SEQ ID NO:4, classified in class 530, subclass 387.7.

The Examiner also required election between the polynucleotides of SEQ ID NO:1 or 3 (Groups VI and VII) and the polypeptides of SEQ ID NO:2 and 4 (Groups VIII and IX).

Applicants wish to point out an Examiner's error in the characterizations of Groups II and III. Group II (Claims 4-7) is drawn to methods of modulating a physiological signal by contacting an IL-1R6 receptor expressing cell with an agonist or antagonist of IL-1delta or IL-1epsilon. It is not correct to characterize, or limit, Group II as drawn to methods using an antibody. Group III (Claims 8-11) is drawn to a method of modulating a signal to a cell mediated by IL-1delta or IL-1epsilon, comprising contacting the cell with an agonist or antagonist of IL-1R6. It is not correct to characterize, or limit, Group III as drawn to methods using an antibody.

Applicants wish to point out another error in the Restriction Requirement. The Examiner wrote of "the polypeptides of SEQ ID Nos.3 and 4 (Groups VIII and IX)," whereas the correct version should be "the polypeptides of SEQ ID Nos. 2 and 4 (Groups VIII and IX)." (page 4, line 17 of Office action).

Applicants provisionally elect, with traverse, Group III, drawn to methods of modulating a physiological signal by contacting an IL-1R6 receptor bearing cell with an agonist or antagonist (including an antibody) to IL-1R6. Group III comprises Claims 8-11, as filed. Applicants also elect SEQ ID NO:4, human IL-1epsilon polypeptide.

Applicants traverse the Restriction Requirement. Applicants request that the claims of Groups II and III, as they relate to IL-1epsilon, be rejoined. Group II comprises Claims 4-7, as filed. Applicants traverse the Restriction Requirement on the grounds that no serious burden would exist to examine claims encompassed by Groups II and III together.

Applicants submit that the method of using the antibodies of Groups II and III can inhibit the same interaction, i.e., the binding of IL-1epsilon to its receptor, IL-1R6. In view of the Examiner's suggestion that to "monitor the endpoints" is a criterion used in restriction practice (page 4 of Office action), Applicants contend that Groups II and III share the same endpoint, i.e., in modulating cell signaling. Thus, rejoinder of Groups II and III, as they relate to IL-1epsilon, is requested.

In view of the above, Applicants believe that it would not be a serious burden to examine the claims in the above-identified groups together, and that the Examiner must therefore examine them together (MPEP §803; August 2001).

Applicants will address the issue of inventorship for the elected claims and amend inventorship appropriately if the Restriction Requirement should be made final.

Applicants reserve the right to file subsequent applications claiming the non-elected subject matter and do not waive any of their rights or abandon any non-elected subject matter. Since Applicants have fully and completely responded to the Restriction Requirement and have made the required election, this application is now in order for early action.

Applicants believe that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239. If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

Date: August 30, 2002

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